

**REMARKS**

Applicant respectfully request entry of the foregoing amendments and reconsideration of this application in view of the reasons that follow.

**I. STATEMENT REGARDING INTERVIEW UNDER 37 C.F.R. § 1.133(B)**

Applicants' Representative thanks Examiner Tsay and Supervisory Patent Examiner M. Rao for the helpful and courteous interview of September 14, 2010. During the interview, Applicants' Representative proposed the amendments presented herein. The Examiners agreed that the amendments would result in favorable reconsideration of the application, because omitting the correlating limitation and adding a lower limit of 2% would overcome the Chtourou reference. The substance of the interview is set forth in more detail below.

**II. DISPOSITION OF THE CLAIMS**

Withdrawn claims 1-6, 11-15, and 18 have been canceled.

Claim 7 is currently being amended. No new matter has been added. The specification supports the amendment to claim 7 in the Examples. Specifically, the added limitation "vWF hexadecamers and higher multimers is at least 2% in the filtrate" is supported by the disclosure of "16 mers and +" (see pages 2-3, Tables I-IV) and "Multimers 16+" (see page 4, Table V) and by the "2%" disclosure in Table II, row 4 (see page 3).

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 7-9 and 16-17 are now pending in this application.

### III. INDEFINITENESS

Applicants traverse the indefiniteness rejection for the record.

To advance prosecution, however, Applicants have obviated the rejection by amendment. The “correlating” step has been removed, as suggested by the Examiners.

### IV. NOVELTY AND NONOBVIOUSNESS

As explained during the interview, the claims as amended are novel and nonobvious over US 6,967,239 (“Chtourou”).

Specifically, Chtourou fails to disclose or suggest the added limitation “vWF hexadecamers and higher multimers is at least 2% in the filtrate”.

Instead, Chtourou repeatedly emphasizes that the disclosed Factor VIII solution is “devoid of high molecular weight vWF” (see column 1, lines 7-11; column 2, lines 40-45, 48-40, 52-53, 60-61; column 5, lines 18-20; and sentence bridging columns 9-10). In particular, Table 7 of Chtourou discloses zero “wWF multimers  $\geq 15$ ” after filtration (emphasis added; column 9):

TABLE 7

	Before filtration	After filtration
FVIII (IU/ml)	37	7.9
vWF (IU/ml)	5.6	0.39
vWF/FVIII	0.33	0.05
wWF multimers $\geq 15$	32%	—
vWF multimers $\geq 10$	22.4%	3.2%
vWF multimers $\geq 5$	71.5%	35.6

If the amount of vWF multimers  $\geq 15$  is zero, then the limitation “vWF hexadecamers and higher multimers is at least 2% in the filtrate” of claim 7 as presently amended cannot be satisfied. In other words, if that amount of vWF pentadecamers and higher multimers is zero, then the amount of vWF hexadecamers and higher multimers is necessarily also zero.

Regarding obviousness, Chtourou's repeated emphasis on total removal of high molecular weight vWF renders the present claims nonobvious. Chtourou nowhere suggests or implies that retaining high molecular weight vWF could be acceptable. This reasoning applies whether Chtourou is considered as prior art for the purposes of obviousness or as a potential candidate for an obviousness-type double patenting (ODP) rejection.

Regarding ODP, Applicants note that Chtourou's claims recite "wherein the filtered solution is ... devoid of high molecular forms of vWF". Thus, the present claims as amended are necessarily also nonobvious over Chtourou's claims. Accordingly, the present claims should not be subject to an ODP rejection.

Accordingly, the claims as amended are novel and nonobvious over Chtourou.

### **CONCLUSION**

Applicant respectfully request entry of this amendment, because doing so would raise no new issues, would require no further search, and would place the application in condition for allowance.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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